

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: 020740/S002**

**STATISTICAL REVIEW(S)**

M. Simoneau

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: November 18, 1998

FROM: Mathematical Statistician, Division of Biometrics II (HFD-715)

SUBJECT: Statistical Review not needed for this supplement

TO: File (NDA 20-740/013)

I talked to Dr. Orloff (HFD-510) about the need for a statistical review of the comparisons between 400  $\mu$ g Baycol and 300  $\mu$ g Baycol in trials 0149 and 0162. He stated that statistical superiority of 400  $\mu$ g need not be demonstrated since the addition to the label simply informs the physician that it is reasonable to titrate a patient up to that level. No population-based inference about any "superior efficacy" of 400  $\mu$ g is necessary. Consequently, he stated that a formal statistical review is not necessary.

/S/

David Hoberman, Ph.D.

Concur: Dr. Sahlroot

/S/

11/25/98

cc:

Orig. NDA #

HFD-510/division file, DOrloff, SSobel, SShen, MSimoneau

HFD-715/DHoberman, TSahlroot, division file, chron

APPEARS THIS WAY ON ORIGINAL